
Agenzia Italiana del Farmaco

AIFA

Certificate No: IT-API/163/H/2017

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**

**Part 1**

**Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC**

The competent authority of Italy confirms the following:
The manufacturer I.M.S. S.R.L.
Site address Via Venezia Giulia, 23 (loc. MILANO) - 20157 MILANO (MI)

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: **D.L. n. 219 of 24th April 2006 art. 53**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2017/09/22, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.
The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

AIFA - Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of APIs Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+39065978401 Fax +390659784617
website: www.agenziafarmaco.it
SIS : 1703

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Part 2

# Name and address of the site:

## I.M.S. S.R.L. - Via Venezia Giulia, 23 (loc.MILANO), 20157 MILANO (MI)

| Name of the active Substances manufactured or imported: |
|---|
| ACTIVE SUBSTANCES (NON-STERILE AND OF NON- BIOLOGICAL ORIGIN) |
| ACTIVE SUBSTANCES (STERILE AND/OR BIOLOGICAL ORIGIN) |

## 3. Manufacturing Operations - Active Substances

### 3 - Manufacturing Operations - Active Substances
### ACTIVE SUBSTANCES (NON-STERILE AND OF NON- BIOLOGICAL ORIGIN)

| | |
|---|---|
| **3.5** | **General Finishing Steps** |
| | **3.5.1.** Physical processing steps<br>milling/micronisation<br>Special Requirements<br>Other: Hormones or substances with hormonal activity<br>**3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>**3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) |
| **3.6** | **Quality Control Testing** |
| | **3.6.1.** Physical / Chemical testing |

### 3 - Manufacturing Operations - Active Substances
### ACTIVE SUBSTANCES (STERILE AND/OR BIOLOGICAL ORIGIN)

| | |
|---|---|
| **3.5** | **General Finishing Steps** |
| | **3.5.1.** Physical processing steps<br>milling/micronisation |

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| | |
|---|---|
| | **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>**3.5.3.** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) |
| **3.6** | **Quality Control Testing** |
| | **3.6.1.** Physical / Chemical testing |

## Restrictions or clarifying remarks:

The Inspectorate adopted a risk-based approach for planning of inspections, therefore the validity of the GMP certificate for this manufacturing site is not more than 48 months from the last general GMP inspection, which was conducted on 2016/12/02. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.No batch certification, no sterile active substances.

Rome, 2017/12/01

Name and signature of the authorised person of the Competent Authority of Republic of Italy

Dott.ssa Marisa Delbò

*AIFA - GMP Inspections and Manufacturing Authorizations of APIs Office*

**This is a certfied copy of the certificate issued on , 2017/12/01 consisting of 3 sheets; the validity of the reprinted GMP certificate is the same as the original certificate and is indicated in paragraph Restriction or clarifying remarks.**

**For ratification**

*Aifa-GMP Inspection and Manufacturing Authorizations of APIs Office*
Dott.ssa Marisa Delbò

Rome, 2017/12/20

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